

PATENT APPLICATION

CATHETER WITH SIDE SHEATH AND METHODS

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CATHETER WITH SIDE SHEATH

CROSS-REFERENCES TO RELATED APPLICATIONS

This application is a continuation in part application of U.S. Patent
5 Application Serial No. 09/614,472, filed July 11, 2000, which is a continuation in part
application of U.S. Patent Application Serial Nos. 09/325,996, filed June 4, 1999, and
09/455,299, filed December 6, 1999 the complete disclosures of which are herein
incorporated by reference.

10 TECHNICAL FIELD

The present invention relates to catheter systems for delivering stents.

BACKGROUND OF THE INVENTION

15 A type of endoprosthesis device, commonly referred to as a stent, may be
placed or implanted within a vein, artery or other tubular body organ for treating
occlusions, stenoses, or aneurysms of a vessel by reinforcing the wall of the vessel or by
expanding the vessel. Stents have been used to treat dissections in blood vessel walls
caused by balloon angioplasty of the coronary arteries as well as peripheral arteries and to
improve angioplasty results by preventing elastic recoil and remodeling of the vessel
20 wall. Two randomized multicenter trials have recently shown a lower restenosis rate in
stent treated coronary arteries compared with balloon angioplasty alone (*Serruys, PW
et al.*, New England Journal of Medicine 331: 489-495 (1994) and *Fischman, DL et al.*
New England Journal of Medicine 331:496-501 (1994)). Stents have been successfully
implanted in the urinary tract, the bile duct, the esophagus and the tracheo-bronchial tree
25 to reinforce those body organs, as well as implanted into the neurovascular, peripheral
vascular, coronary, cardiac, and renal systems, among others. The term "stent" as used in
this Application is a device which is intraluminally implanted within bodily vessels to
reinforce collapsing, dissected, partially occluded, weakened, diseased or abnormally
dilated or small segments of a vessel wall.

30 One of the drawbacks of conventional stents is that they are generally
produced in a straight tubular configuration. The use of such stents to treat diseased
vessels at or near a bifurcation (branch point) of a vessel may create a risk of

compromising the degree of patency of the main vessel and/or its branches, or the bifurcation point and also limits the ability to insert a branch stent into the side branch if the result of treatment of the main, or main, vessel is suboptimal. Suboptimal results may occur as a result of several mechanisms, such as displacing diseased tissue, plaque shifting, vessel spasm, dissection with or without intimal flaps, thrombosis, and embolism.

As described in related co-pending U.S. Patent Application Nos. 08/744022 filed 11/04/96 (now abandoned); 09/007265 filed 01/14/98; 08/935,383 filed 9/23/97; and 60/088301 filed 06/05/98; and PCT Patent Application Publication No. WO 99/00835 filed 01/14/98; systems have been developed for deploying a main stent in a main vessel at the intersection of a main vessel and a branch vessel. Further, a branch stent may be positioned within a branch vessel through a side opening in the main stent. As will be appreciated, such tasks may be challenging.

For example, management of two guidewires used in introducing and/or orienting stents can pose particular challenges, such as the tendency of the guidewires to twist together. As another example, imaging placement of the stents using low-cost and convenient techniques, such as x-ray or ultrasound imaging, can be difficult using existing methods.

SUMMARY OF THE INVENTION

The invention provides systems and methods for deploying a main vessel stent in a main vessel, with a side hole in the main stent being in registry with the ostium of a branch vessel. The invention also provides techniques for positioning a branch stent in the branch vessel by passing the branch stent through the side hole of the main vessel stent. A variety of catheter designs may be employed to deploy and position the main and branch vessel stents. Such catheters may be used in connection with a pair of guidewires that terminate in the main and branch vessels. These guidewires may be used to facilitate introduction of the catheter, any stents, and/or to properly orient the stent within the vessel. For example, the branch vessel guidewire may be used alone or in combination with other elements of the catheter to assist in aligning the side hole of the main stent and/or to deploy a branch vessel stent.

In one particular embodiment, a catheter system utilizes a catheter comprising a catheter body having a distal end, a proximal end, a main vessel guidewire lumen that is adapted to receive a main vessel guidewire and a balloon disposed near the

distal end of the catheter body. The catheter further comprises a side member disposed adjacent to the catheter body. The side member has a distal end, a proximal end, and a branch vessel guidewire lumen that is adapted to receive a branch vessel guidewire. A stent having a side hole is disposed over the balloon. Further, a distal portion of the side member is positioned between at least a portion of the stent and the balloon. The distal end may remain disposed beneath the stent during insertion, and then advanced through the side hole once properly positioned at the bifurcation. Alternatively, the distal end of the side member may extend out of the side hole during insertion. In either case, the distal end of the side member may be used to properly position the main vessel stent and/or to deploy a branch vessel stent.

In one aspect, such a catheter system facilitates placement of the stent within the main vessel, with the side hole being in registry with an ostium of a branch vessel. This may be accomplished, for example, by advancing a main vessel guidewire in the main vessel until passing the branch vessel. The catheter is then advanced over the main vessel guidewire until the stent reaches or is proximal to the branch vessel. At this point, a branch vessel guidewire may be introduced through the branch vessel lumen of the side member. The branch vessel guidewire is advanced out of the side member and into the branch vessel to assist in aligning the side hole with the ostium of the branch vessel prior to deployment of the stent in the main vessel. To assist in guiding the branch vessel guidewire into the branch vessel, the side member may taper to a narrow distal end, which may also be curved slightly outwardly. One advantage of such a catheter system is that a single guidewire may be used to introduce the catheter. The catheter then serves as a guide for the branch vessel guidewire.

In an alternative aspect, both of the guidewires may be inserted into the main and branch vessels to permit the catheter to be advanced over the pre-inserted guidewires. As another alternative, the catheter may be loaded onto both guidewires to permit the guidewires and the loaded catheter to be introduced as a combined system. In such a case, the system may be advanced until reaching the end of a guide catheter. The guidewires may then be advanced out of the guide catheter and into the main and branch vessels. With the guidewires in place, the catheter may be further advanced to force the side member into the branch vessel and to align the side hole with the ostium of the branch vessel. In cases where the distal tip of the catheter is sufficiently flexible, the catheter may be advanced to the vessel bifurcation before extending the guidewires.

Alignment of the side hole with the ostium may be accomplished in a variety of ways. For example, introduction of the branch vessel guidewire into the branch vessel may sufficiently align the side hole with the ostium. Other alignment techniques may depend on the configuration of the side member. For example, in some cases the side member may comprise a flexible sheath that is movably coupled to the catheter body, e.g., by passing through a lumen of a truncated connector that is coupled to the catheter body. Once the branch vessel guidewire is advanced into the branch vessel, the sheath may be advanced into the branch vessel to move the side hole into registry with the ostium. Conveniently, the catheter body and the side member may be fabricated from pebax and graphite to facilitate relative movement between the catheter body and the side member.

In other cases, the flexible sheath may be fixedly coupled to the catheter body, except at the distal end. For example, the length over which the distal end of the side member is unattached to the distal end of the main catheter may be approximately 2 to approximately 10 cm to aid with the final rotation of the stent body for alignment with the ostium without compromising the pushability of the delivery system. With this configuration, once the branch vessel guidewire is in place, the catheter may be further advanced over both guidewires, with the distal end of the side member extending further into the branch vessel, thereby aligning the side hole with the ostium in the three dimensional space.

A variety of techniques may be used to ensure that the distal end of the side member is properly advanced into the branch vessel. For example, the side hole in the main vessel stent may be aligned with the ostium of the branch vessel by viewing relative movement of radiopaque markers positioned on the catheter body and the side member. The relative marker movement indicates that the distal portion of the side member is advancing into the ostium of the branch vessel over the branch vessel guidewire while the catheter body proceeds through the main vessel.

Such relative movement of the radiopaque markers may be viewed as a rotation of a marker positioned on the side member with respect to one or more markers positioned on the catheter body, or as a separation between the marker on the side member with respect to one or more markers on the main catheter. In one aspect, markers may be positioned at the distal ends of the side member and the catheter body, such that the separation between these markers will be relatively large, and thus can be easily viewed. Moreover, when the markers are positioned at the distal ends of the main vessel

stent and side member, the surgeon will view the separation of these markers earlier than would be the case if these markers were disposed at a more proximal location.

Conveniently, a plurality of markers may be positioned on the catheter body, with markers positioned at locations corresponding to the proximal and distal ends of the main vessel stent. A medial marker may also be included, positioned somewhere halfway between the distal and proximal markers, for indicating the position of the side hole in the main vessel stent, (which may be positioned anywhere between the distal and proximal ends of the stent).

The relative movement of the markers positioned on the catheter body and those positioned on the side member may be observed fluoroscopically. Conveniently, the markers may be constructed of radiopaque materials, such as tungsten, platinum or gold. In one option, the distal end of the side member may be fabricated from a fluoroscopically visible material, such as tungsten.

Once the stent is properly positioned, the balloon may be inflated to deploy the stent. Conveniently, the catheter body may include a balloon inflation lumen to permit the balloon to be inflated.

In another aspect, the catheter system may be used to deploy a branch vessel stent within the branch vessel following deployment of the main vessel stent. A variety of techniques may be used to deploy the branch vessel stent. For example, if the side member is slidably coupled to the catheter body, the side member may be provided with a balloon at the distal end, with the branch stent being coupled over the balloon. In this way, the side member may be advanced into the branch vessel and the balloon inflated to deploy the branch stent. As another example, the side member may be retracted from the main vessel while the branch vessel guidewire is kept in place. A stent deployment device having a balloon and a branch stent disposed over the balloon may then be advanced over the branch guidewire and into the branch stent. The branch stent may then be deployed by inflating the balloon. In another option, the main vessel stent may be only partially expanded to permit the branch stent to be deployed through the main vessel stent. Once the branch vessel stent is in place, the main vessel stent may be fully deployed.

In cases where the side member is fixedly attached to (or integrally formed with) the catheter body, the distal end of the side member may include a balloon, with the

branch stent being disposed over the balloon. The catheter may be advanced over the two guidewires until the branch stent is distally positioned within the branch vessel. The main stent may then be deployed, and the entire device pulled back until the branch stent is appropriately positioned. The balloon on the side member may then be inflated to deploy the branch stent. In another option, the entire catheter may be withdrawn from the patient while at least the branch guidewire is left in place. A stent deployment device may then be advanced into the branch vessel in a manner similar to that just described.

In one particular aspect, the catheter system may further include a proximal end hub having a main vessel guidewire channel that is coupled to the main vessel guidewire lumen, a branch vessel guidewire channel that is coupled to the branch vessel guidewire lumen, and a balloon inflation port that is coupled to the balloon inflation lumen. In one aspect, the first and second guidewire channels may be separated by about zero to about 20° to aid wire movement without hindering device preparation for use. For example, such an angle facilitates the attachment of syringes while also ensuring that the guidewires are not too separated.

The main vessel stent may optionally include outwardly expandable portions which can be expanded from an initial position which is flush with the cylindrical body of the stent to protrude outwardly from the side hole. Such a configuration may be used to anchor the stent into the walls of the branch vessel to hold the side opening in registry with the ostium of the branch vessel. In an exemplary aspect, the cylindrical body of the main vessel stent may have an even surface and an expandable portion that is positioned within the side hole of the cylindrical body, such that the expandable portion is flush with the cylindrical body prior to expansion.

In one aspect, the branch stent may optionally comprise a contacting portion at its proximal end to secure the proximal end of the branch stent to the side hole in the main vessel stent. In an exemplary aspect, the contacting portion comprises a flared proximal end.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 illustrates one embodiment of a catheter having a catheter body and a side member movably coupled to the catheter body according to the invention.

Fig. 2 illustrates the placement of a main vessel guidewire into a main vessel according to the invention.

Fig. 3 illustrates the advancement of the catheter of Fig. 1 over the guidewire of Fig. 2.

5 Fig. 4 illustrates the catheter of Fig. 1 after a branch vessel guidewire has been introduced through the side member and into a branch vessel

Fig. 5 illustrates the catheter of Fig. 1 after the branch guidewire has been introduced into the branch vessel, and after the side member has been withdrawn.

10 Fig. 6 illustrates the introduction of a branch stent deployment device over the branch vessel guidewire after the main stent is deployed.

Fig. 7 illustrates the deployment of a branch stent using the deployment device of Fig. 6.

Fig. 8 illustrates an alternative catheter having a catheter body and a side member with a balloon at a distal end.

15 Fig. 9 illustrates the catheter body and stent deployment device of Fig. 6.

Fig. 10 illustrates an alternative embodiment of a catheter having a catheter body and a side member that is fixably attached to the catheter body according to the invention.

Fig. 11 is a more detailed view of a distal end of the catheter of Fig. 10.

20 Fig. 12 is a cross sectional side view of the distal end of the catheter of Fig. 11.

Fig. 13 illustrates the introduction of the catheter of Fig. 10 into a main vessel according to the invention.

25 Fig. 14 illustrates the advancement of a branch vessel guidewire into a branch vessel using the catheter of Fig. 10.

Fig. 15 illustrates the introduction of a distal end of the side member into the branch vessel to facilitate alignment of a side hole with the ostium of the branch vessel.

Fig. 16 is a cross sectional view of the catheter of Fig. 15.

5 Fig. 17 illustrates the deployment of a branch vessel stent into a branch vessel using the catheter of Fig. 10 with a modified side member according to the invention.

10 Fig. 18 illustrates a technique for deploying a branch vessel stent over a branch vessel guidewire following deployment of a main vessel stent according to the invention.

Fig. 19 illustrates inflation of a balloon on a balloon deployment device in order to deploy the branch vessel stent.

15 Fig. 20 illustrates an alternative embodiment of a main vessel stent having laterally deployable portions that may be deployed using the stent deployment device of Figs. 7 and 18.

Fig. 21 illustrates another embodiment of a catheter for deploying a main vessel stent according to the invention.

Fig. 22 is a cross sectional side view of the catheter of Fig. 21 taken along lines 22-22.

20 Fig. 23 is a cross sectional side view of a hub of the catheter of Fig. 21.

Fig. 24 illustrates a kit having the catheter of Fig. 21 and a set of instructions for using the catheter.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

25 The present invention provides systems and methods for positioning a pair of guidewires in main and branch vessels at a vessel bifurcation to facilitate positioning and deployment of one or more stents, such as a main vessel stent or a branch vessel

stent. The systems and methods may also be used to align a side hole in a main vessel stent in registry with the ostium of a branch vessel.

Applications of the invention include the cardiac, coronary, renal, peripheral vascular, gastrointestinal, pulmonary, urinary and neurovascular systems and the brain. Advantages of the invention include, but are not limited to, the use of an improved stent delivery apparatus, which may deliver main vessel and branch vessel stents to: 1) completely cover the bifurcation point of bifurcation vessels; 2) be used to treat lesions in one branch of a bifurcation while preserving access to the other branch for future treatment; 3) allow for differential sizing of the stents in a bifurcated stent apparatus even after a main stent is implanted; 4) treat bifurcation lesions in a bifurcated vessel where the branch vessel extends from the side of the main vessel; and 5) be marked with, or at least partly constructed of, material which is imageable by commonly used intraluminal catheterization visualization techniques including but not limited to ultrasound or x-ray.

As described herein, a side hole in the main vessel stent refers to a relatively large hole which is intended to be aligned with the ostium of the branch vessel. Such a side hole is separate from any of the multiple passageways extending through the side of the stent between struts in the stent geometry. Accordingly, the side hole in the stent is a hole which is understood to be larger than other passages through the stent. In some aspects, this side hole is defined by a band of continuous material which defines the perimeter of the side hole. This continuous band of material preferably comprises discontinuities over its length so that the area of the side hole expands together with the expansion of the stent. In various aspects, the continuous band comprises protrusions which project inwardly from a peripheral edge of the side opening. Preferably, these protrusions (or expandable portions) are initially aligned within a cylindrical envelope of the tubular body of the stent.

Referring now to Fig. 1, one embodiment of a catheter 10 will be described. Catheter 10 comprises a catheter body 12 and a side member 14 that is adjacent to catheter body 12. Integrally formed with catheter body 12 is a connector 16 having a lumen 18 into which side member 14 is slidably received. In this way, side member 14 is movable with respect to catheter body 12. To facilitate sliding of side member 14 in lumen 18, connector 16 may be constructed of pebax with graphite. Alternatively, the inner surface of lumen 18 may have metal powders, glass beads, Teflon power, imbedded inorganic fibers, or the like.

Catheter body 12 has a proximal end 20 and a distal end 22. Extending between proximal end 20 and distal end 22 is a guidewire lumen 24 to permit a guidewire to be inserted through catheter body 12. Catheter body 12 is constructed of a flexible material to permit catheter body 12 to traverse through vessels in the body. An annular balloon inflation lumen (not shown) is disposed about guidewire lumen 24 to permit a balloon 26 at distal end 22 to be inflated. As illustrated in Fig. 3, a stent 28 (omitted from Fig. 1 for convenience of illustration) is crimped about balloon 26. In this way, balloon 26 may be inflated to deploy stent 28. At proximal end 20 is a guidewire port 30 that leads to guidewire lumen 24, and a balloon inflation port 32 that leads to the balloon inflation lumen.

Side member 14 has a proximal end 34 and a distal end 36. Extending between proximal end 34 and distal end 36 is a guidewire lumen (hidden from view) that is configured to receive a branch vessel guidewire. Side member 14 is constructed as a flexible sheath to permit side member 14 to navigate through a patient's vessels. Conveniently, distal end 36 may be tapered to facilitate introduction of distal end 36 into a branch vessel.

Catheter 10 may be used to introduce a stent into a main vessel, with a side hole of the stent being aligned with an ostium of a branch vessel. Optionally, catheter 10 may also be used to facilitate the introduction of a branch stent into a branch vessel. To accomplish such tasks, catheter 10 utilizes a pair of guidewires, conveniently referred to as main vessel and branch vessel guidewires, that terminate in a main vessel and a branch vessel of a patient. A variety of techniques may be used to introduce the guidewires and catheter 10 into the patient. For example, the main vessel guidewire may first be introduced into the main vessel. Catheter 10 may then be loaded onto the main vessel guidewire and introduced into a patient. Once in place, the branch vessel guidewire may be passed through the guidewire lumen of side member 14. As an alternative, both guidewires may initially be introduced into the patient. Catheter 10 may then be loaded onto both guidewires and introduced into the patient. As a further alternative, catheter 10 may be loaded onto both guidewires such that the distal ends of the guidewires extend slightly past distal ends 22 and 36. Catheter 10 and the guidewires may then be introduced into the patient as a single unit.

Referring now to Figs. 2-4, one method of introducing stent 36 into a main vessel MV of a patient will be described. Initially, a main vessel guidewire 38 is inserted into main vessel MV using techniques known in the art (see Fig. 2). Guidewire 38 is

moved in a direction D until a distal end 40 of guidewire 38 extends beyond the intersection of main vessel MV and a branch vessel BV.

As shown in Fig. 3, catheter 10 is loaded onto guidewire 38 such that guidewire 38 passes through lumen 24 and is advanced in direction D until stent 28 reaches the ostium of branch vessel BV. Stent 28 includes a side hole 42 that is placed in the vicinity of the ostium of branch vessel BV. Stent 28 is crimped to balloon 26 such that distal end 36 of side member 14 is positioned between stent 28 and balloon 26 and terminates at side hole 42. In this way, distal end 36 is stored beneath stent 28 to permit catheter 10 to be routed through main vessel MV without interference from distal end 36 and while using only a single guidewire.

To facilitate alignment of side hole 42 with the ostium of branch vessel BV, distal end 36 may include tungsten or another radiopaque material to permit fluoroscopic visualization. Hence, a surgeon may stop advancement of catheter 10 when distal end 36 (as viewed under fluoroscopy) reaches branch vessel BV.

As shown in Fig. 4, a branch vessel guidewire 44 may be advanced through the lumen of side member 14 until a distal end 46 passes through side hole 42 and into branch vessel BV. In this way, guidewire 44 may be used to align side hole 42 of stent 28 with the ostium of branch vessel BV. Once properly aligned, balloon 26 may be inflated to deploy stent 28.

Optionally, distal end 36 of side member may be advanced over guidewire 44 and into branch vessel BV before stent 28 is fully displayed to further assist in aligning side hole 42 with the ostium. Further, although the method for deploying stent 28 has been described using a single guidewire to introduce catheter 10 into the patient, it will be appreciated that both guidewires may be used as previously described.

With stent 28 partially or fully deployed, catheter 10 may be used to facilitate the deployment of a branch vessel stent 48 as illustrated in Figs. 5-7. As shown in Fig. 5, side member 14 is withdrawn from main vessel MV, leaving branch vessel guidewire 44 in place. As shown in Fig. 6, a stent deployment device 50 having a branch vessel stent 48 attached thereto is introduced over branch vessel guidewire 44 until branch vessel stent 48 extends out of side hole 42. Stent deployment device 50 comprises an elongate flexible body 52 having a proximal end 54 and a distal end 56. Extending between proximal end 54 and distal end 56 is a guidewire lumen to permit body 52 to be inserted over guidewire 44. Disposed at distal end 56 is a balloon 58 over which stent 48 is positioned. Flexible body 52 further includes a balloon inflation lumen to permit

balloon 58 to be inflated from outside of the patient. Once branch vessel stent 48 extends into branch vessel BV, balloon 58 may be inflated to deploy branch vessel stent 48 within branch vessel BV as illustrated in Fig. 7. Optionally, branch vessel stent 48 may include a contact portion 60 that remains disposed within stent 28 to secure a proximal end of branch vessel stent 48 to side hole 42 of stent 28. In this way, a bifurcated stent arrangement is provided which extends both into the main vessel MV and branch vessel BV. After main vessel stent 28 and branch vessel stent 48 have been deployed, catheter body 12 and stent deployment device 50 may be withdrawn from the patient leaving a bifurcated support at the intersection of main vessel MV and branch vessel BV as illustrated in Fig. 8.

As an alternative to using catheter body 12 and side member 14 in combination with stent deployment device 50 to deploy branch vessel stent 48 in combination with main vessel stent 28, catheter body 12 may be used in combination with stent deployment device 50 alone to accomplish such features. A combination of stent deployment device 50 with catheter body 12 is illustrated in Fig. 9. For convenience of illustration, both main vessel stent 28 and branch vessel stent 48 have been omitted from view. With such a configuration (as shown in Fig. 6), catheter body 12 and stent deployment device 50 may be introduced into the patient over guidewires 38 and/or 44 using any of the techniques previously described. After stent 28 has been introduced into the area of bifurcation, guidewire 44 and/or distal end 56 of stent deployment device 50 may be used to align side hole 42 with the ostium of branch vessel BV. Distal end 56 of stent deployment device 50 may be positioned within branch vessel BV in a manner similar to that described in connection with Fig. 7. Branch vessel stent 48 may then be deployed in a manner similar to that previously described by inflating balloon 58 using a balloon inflation port 62. In this way, branch vessel stent 48 may be deployed without having to withdraw side member 14 prior to introduction of stent deployment device 50.

Referring now to Fig. 10, another embodiment of a stent delivery catheter 64 will be described. Catheter 64 comprises a catheter body 66 and a side member 68 that is attached to catheter body 66. Both catheter body 66 and side member 68 are constructed of a flexible material to permit catheter 64 to traverse through the tortuous vessels of the human body. Catheter body 66 has a proximal end 70 and a distal end 72. Extending between proximal end 70 and distal end 72 is a guidewire lumen (hidden from view) for receiving a guidewire. At the proximal end 70 is a guidewire port 74 and a balloon inflation port 76. Also extending through catheter body 66 is a balloon inflation

lumen that permits a balloon 78 at distal end 72 to be inflated using balloon inflation port 76.

Side member 68 has a proximal end 80 and a distal end 82. Extending between proximal end 80 and distal end 82 is a guidewire lumen (hidden from view) for receiving another guidewire. Side member 68 is fixably attached to catheter body 66 except at distal end 82 where side member 68 is separated from catheter body 66. Conveniently, catheter body 66 and side member 68 may be formed as an integral unit. In one aspect, the portion of distal end 82 that is detached from catheter body 66 is in the length from about 2 cm to about 10 cm. Side member 68 may further include a guidewire port 84 to facilitate introduction of a guidewire into the guidewire lumen.

As best shown in Fig. 11, a main vessel stent 86 is crimped about balloon 78. In this way, main vessel stent 86 may be deployed upon inflation of balloon 78. As further illustrated in Fig. 11, main vessel stent 86 includes a side hole 88 that may be aligned with an ostium of a branch vessel in a manner similar to that previously described with other embodiments. Main vessel stent 86 further includes a proximal end 90 and a distal end 92. Distal end 82 of side member 68 passes between stent 86 and balloon 78 at proximal end 90. Distal end 82 of side member 68 further extends through side hole 88 so that it is outside of stent 86. Such a configuration permits distal end 82 to be advanced into a branch vessel prior to deployment of main vessel stent 86 to facilitate alignment of side hole 88 with the ostium of the branch vessel.

Catheter 64 further includes a proximal marker 94, a medial marker 96 and a distal marker 98 that are disposed on catheter body 66. Conveniently, the location of proximal marker 94 may correspond to the location of proximal end 90 of stent 86. The location of distal marker 98 may correspond to the location of distal end 92 of stent 86. Further, the location of medial marker 96 may correspond to the location of side hole 88. Side member 68 may further include at least one marker that is positioned on distal end 82. As shown, a marker 100 is aligned with side hole 88, and a marker 102 is aligned with distal end 92 of stent 86. Each of the markers may be constructed of a fluoroscopically visible material to permit visualization of the markers during a deployment procedure. As described in greater detail hereinafter, use of markers on both catheter body 66 and side member 68 provides the surgeon with information as to when distal end 82 is entering into a branch vessel while distal end 72 of catheter body 66 is advancing further into the main vessel. Conveniently, each marker may be slightly elongated and rectangular in shape. Examples of materials that may be used to construct

the markers include tungsten, gold or the like. A more detailed view of the markers is illustrated in Fig. 12.

Referring now to Figs. 13-16, one method for introducing stent 86 into a main vessel, with side hole 88 being aligned with an ostium of a branch vessel, will be described. Initially, a main vessel guidewire 104 is introduced into main vessel MV until a distal end 106 extends past a vessel intersection I between branch vessel BV and main vessel MV. Catheter 64 is then loaded onto guidewire 104 and introduced into main vessel MV, with guidewire 104 extending through the guidewire lumen of catheter body 66. A branch vessel guidewire 108 is also introduced into side member 68 such that a distal end 110 of branch vessel guidewire 108 extends beyond distal end 82 of side member 68. In this way, distal end 82 has sufficient rigidity to track through main vessel MV. Alternatively, branch vessel guidewire 108 could be introduced into main vessel MV until distal end 110 extends into branch vessel BV. Catheter 64 may then be loaded onto both guidewires and tracked over both guidewires until in the position shown in Fig. 13. As another alternative, catheter 64 may be loaded onto guidewires 104 and 108 such that distal ends 106 and 110 extend just distally of catheter 64. Catheter 64 and guidewires 104 and 108 may then be simultaneously introduced upon to the distal edge of a guiding catheter where the guidewires may then be advanced.

As shown in Fig. 14, prior to deployment of main vessel stent 86, distal end 110 of branch vessel guidewire 108 is positioned into branch vessel BV. This may be accomplished, for example, by advancing guidewire 108 out of distal end 82 until reaching branch vessel BV. As previously described, branch vessel guidewire 108 may be preinserted into branch vessel BV so that such an advancing step is not needed. As catheter 64 is further advanced into main vessel MV in the direction of arrow D, branch vessel guidewire 108 serves to align side hole 88 with the ostium of branch vessel BV. Further, distal end 82 of side member 68 passes into branch vessel BV to further ensure alignment of side opening 88 with the ostium of branch vessel BV.

As shown in Figs. 15 and 16, catheter 64 is advanced into main vessel MV, and fluoroscopic viewing equipment may be used to fluoroscopically view markers 94, 96, 98, 100 and 102. Movement of markers 100 and 102 relative to markers 94, 96 and 98 is an indicator that distal end 82 is advancing into branch vessel BV while catheter body 66 is advancing in the main vessel MV. For example, as distal end 82 begins to enter into branch vessel BV, markers 100 and 102 will begin to separate from markers 94, 96 and 98. In many cases, branch vessel BV will not be aligned in the same plane as

main vessel MV. As such, distal end 82 will rotate relative to distal end 72 of catheter body 66. Use of multiple markers on both distal end 82 and distal end 72 facilitates fluoroscopic visualization of relative movement of the markers when distal end 82 is rotating as it enters into branch vessel BV. Further, by viewing the position of markers 94, 96, and 98, the operator may determine the position of proximal end 90 and distal end 92 of stent 86, as well as the position of side hole 88 with respect to the ostium of branch vessel BV.

Once proper alignment has been determined, balloon 78 may be inflated to deploy stent 86 within the main vessel. Catheter 64 may then be removed from the patient, with stent 86 remaining in position.

As shown in Fig. 17, catheter 64 may be modified to include a balloon 112 at distal end 82 of side member 68. Disposed over balloon 112 is a branch vessel stent 114. In this way, following partial or full deployment of main vessel stent 86 in a manner similar to that previously described, balloon 112 may be inflated to deploy branch vessel stent 114 into branch vessel BV. Following deployment of both main vessel stent 86 and branch vessel stent 114, catheter 64 may be withdrawn from the patient, leaving the two stents in place. Hence, by modifying catheter 64 as illustrated in Fig. 17, catheter 64 may be used to align and deploy main vessel stent 86 in a manner similar to that previously described as well as to deploy a branch vessel stent.

Another technique for introducing a branch vessel stent 116 into branch vessel BV following deployment of main vessel stent 86 using catheter 64 is illustrated in Figs. 18 and 19. Following deployment of main vessel stent 86 in a manner similar to that previously described, catheter 64 is removed from the patient while leaving branch vessel guidewire 108 in place. A stent deployment device 118 having a balloon 120 is then advanced over guidewire 108 until branch vessel stent 116 (which is crimped about balloon 120) enters into branch vessel BV as illustrated in Fig. 18. Balloon 120 is then inflated as illustrated in Fig. 19 to deploy branch vessel stent 116. Balloon 120 may then be deflated and stent deployment device 118 withdrawn from the patient leaving in place main vessel stent 86 and branch vessel stent 116. Conveniently, branch vessel stent 116 may include a contacting portion 122 which remains disposed within side hole 88 to secure the proximal end of stent 116 to side hole 88 of main vessel stent 86. Such a contacting portion is described in PCT Patent Application No. WO 99/00835, filed January 14, 1998, the complete disclosure of which is herein incorporated by reference.

Shown in Fig. 20 is an alternative embodiment of a main vessel stent 124 that has been deployed in a main vessel MV. Conveniently, main vessel stent 124 may be deployed using any of the catheters described herein. After deployment of main vessel stent 124, the catheter is removed while a branch vessel guidewire 126 is kept in place
5 within a branch vessel BV as shown in Fig. 20. Stent deployment device 118 of Fig. 19 may then be employed to deploy radially expandable portions 128 that extend laterally outward from the edges of a side hole 130. In this way, radially expandable portions 128 are pushed against the walls of branch vessel BV, with side hole 130 being positioned in registry with the ostium of branch vessel BV. Stents having radially expandable portions
10 which extend laterally outward in such a manner are described in PCT Application No. WO 99/00835, previously incorporated herein by reference.

Referring now to Fig. 21, an alternative embodiment of a stent delivery catheter 132 will be described. Catheter 132 comprises a catheter body 134 having a proximal end 136 and a distal end 138. Attached to catheter body 134 is a side member
15 140 having a proximal end 142 and a distal end 144. As shown in Fig. 21, distal end 144 of side member 140 is detached from distal end 138 of catheter body 134. The length of distal end 144 that is detached from catheter body 134 may be in the range from about 2 cm to about 10 cm. Such a configuration is advantageous in that it permits distal rotation of the device without rotating the main shaft from the proximal end. In this way, the
20 clinician may easily align the side hole of the main stent with the ostium of the branch vessel without having to rotate the proximal end.

Disposed at distal end 138 is a balloon 146 over which a main vessel stent 148 having a side hole 150 is crimped. Distal end 144 of side member 140 passes
25 between main vessel stent 150 and balloon 146 until exiting side hole 150. In this way, distal end 144 may be positioned within a branch vessel stent in a manner similar to that previously described with other embodiments.

As shown in Fig. 22, passing through catheter body 134 is a main vessel guidewire lumen 152 and a balloon inflation lumen 154 that is disposed about main vessel guidewire lumen 152. Passing through side member 140 is a branch vessel guidewire
30 lumen 156. In this way, catheter 132 may be tracked over main and branch vessel guidewires in a manner similar to that previously described with other embodiments. Further, balloon 146 may be inflated using balloon inflation lumen 154.

As best shown in Figs. 21 and 23, a guidewire hub 158 is coupled to proximal ends 136 and 142. Guidewire hub 158 further includes a main vessel guidewire

port 160, a balloon inflation port 162 and a branch vessel guidewire port 164. Balloon inflation port 162 is in fluid communication with balloon inflation lumen 154 (see Fig. 22) to permit balloon 146 to be inflated and deflated using an inflation device, such as a syringe, that is coupled to port 162. Main vessel guidewire port 160 leads to a main vessel guidewire channel 166, and branch vessel guidewire port 164 leads to a branch vessel guidewire channel 168. In this way, a main vessel guidewire 170 may be passed through port 160, through channel 166 and into guidewire lumen 152 (see Fig. 22). In a similar manner, a branch vessel guidewire 172 may be passed through port 164, through channel 168 and into lumen 156 (see Fig. 22).

Channels 166 and 168 are angled relative to each other, preferably at an angle in the range from about 0 to 20 degrees, and more preferably about 10 to about 20 degrees. By configuring channels 166 and 168 in this manner excessive friction may be avoided when positioning or moving the guidewires within catheter 132. In this way, catheter 132 may more easily be advanced over both guidewires 170 and 172 at the same time. Further, the guidewires are held sufficiently close to permit an operator to simultaneously grasp and hold onto both guidewires with one hand while withdrawing catheter 132 over the two guidewires with the other hand. In addition, the guidewires are held sufficiently far apart to permit a syringe to be coupled to ports 160 and 164, or to permit separate luer fittings to cover ports 160 and 164.

As shown in Fig. 24, catheter 132 may conveniently be included as part of a kit 200. Conveniently, kit 200 may also include instructions for use 202 which sets forth various procedures for deploying main vessel stent 148 using any of the techniques previously described. Instructions for use 202 may be in written or machine readable form. Further, it will be appreciated that kit 200 may alternatively include any of the other catheter embodiments described herein, and instructions 202 may describe any of the method set forth herein.

The invention has now been described in detail for purposes of clarity of understanding. However, it will be appreciated that certain changes and modifications may be practiced within the scope of the appended claims.

WHAT IS CLAIMED IS:

1 1. A catheter system, comprising:
2 a catheter comprising a catheter body having a distal end, a proximal end,
3 a main vessel guidewire lumen that is adapted to receive a main vessel guidewire and a
4 balloon disposed near the distal end of the catheter body, the catheter further comprising a
5 side member disposed adjacent the catheter body, the side member having a distal end, a
6 proximal end, and a branch vessel guidewire lumen that is adapted to receive a branch
7 vessel guidewire;
8 a stent having a side hole through a wall thereof, the stent being disposed
9 over the balloon;
10 wherein a distal portion of the side member is disposed beneath at least a
11 portion of the stent while being adjacent to and moveable with respect to the balloon.

1 2. The catheter system of claim 1, further comprising:
2 at least one radiopaque marker positioned on the catheter body; and
3 at least one radiopaque marker positioned on the side member.

1 3. The catheter system of claim 2, wherein at least one radiopaque
2 marker on the catheter body is adjacent at least one radiopaque marker on the side
3 member.

1 4. The catheter system of claim 2, wherein the radiopaque marker on
2 the catheter body and on the side member are positioned adjacent the side hole in the
3 stent.

1 5. The catheter system of claim 2, wherein the at least one radiopaque
2 marker on the catheter body comprises radiopaque markers positioned at a proximal end
3 and a distal end of the stent.

1 6. The catheter system of claim 2, wherein the at least one marker on
2 the side member is positioned at the distal end of the side member.

1 7. The catheter system of claim 1, wherein the side member
2 comprises a flexible side sheath.

1 8. The catheter system of claim 1, further comprising a branch stent
2 deployment device having a balloon, a guidewire lumen, an inflation lumen that is
3 adapted to supply a fluid to inflate the balloon, and a branch vessel stent disposed over
4 the balloon, wherein the branch stent deployment device is adapted to be advanced over
5 the branch stent guidewire lumen after removal of the side member.

1 9. The catheter system of claim 1, further comprising a connector
2 coupled to the catheter body, wherein the side member extends through the connector so
3 as to be slidably positionable with respect to the catheter body.

1 10. The catheter system of claim 1, wherein the side member is fixedly
2 attached to at least a portion of the catheter body, and wherein the distal end of the side
3 member extends out of the side hole of the stent.

1 11. The catheter system of claim 1, further comprising a balloon
2 disposed at the distal end of the side member.

1 12. The catheter system of claim 1, wherein the distal end of the side
2 member is tapered.

1 13. The catheter system of claim 1, wherein the distal end of the side
2 member is fabricated from a fluoroscopically visible material.

1 14. The catheter system of claim 1, wherein the catheter body and the
2 side member are fabricated from pebax and graphite.

1 15. The catheter system of claim 1, further comprising a branch stent
2 positioned on the side member.

1 16. The catheter system of claim 1, wherein the catheter body further
2 includes a balloon inflation lumen, and further comprising a proximal end hub having a
3 main vessel guidewire channel that is coupled to the main vessel guidewire lumen, a
4 branch vessel guidewire channel that is coupled to the branch vessel guidewire lumen,
5 and a balloon inflation port that is coupled to the balloon inflation lumen.

1 17. The stent delivery system of claim 16, wherein the first and second
2 guidewire channels are separated by about zero to about 20°.

1 18. The stent delivery system of claim 10, wherein the distal end of the
2 side member is unattached to the distal end of the main catheter.

1 19. The stent delivery system of claim 18, wherein the length over
2 which the distal end of the side member is unattached to the distal end of the main
3 catheter is approximately 2 to approximately 10 cm.

1 20. A kit comprising:
2 a catheter system as set forth in claim 1; and
3 instructions for use setting forth a method for positioning the side hole in
4 the stent in registry with the ostium of a branch vessel.

1 21. A method for positioning a main vessel stent at a vessel bifurcation
2 such that a side hole in the main vessel stent is in registry with an ostium of a branch
3 vessel, the method comprising:

4 providing a catheter comprising a catheter body having a distal end, a
5 proximal end, a main vessel guidewire lumen and a balloon disposed near the distal end
6 of the catheter body, with the main vessel stent being disposed over the balloon, and a
7 side member disposed adjacent the catheter body, the side member having a distal end, a
8 proximal end, and a branch vessel guidewire lumen, wherein a distal portion of the side
9 member is disposed beneath at least a portion of the main stent;

10 advancing a main vessel guidewire through a main vessel such that a distal
11 end of the main vessel guidewire extends past the vessel bifurcation;

12 advancing the catheter over the main vessel guidewire, with the guidewire
13 passing through the main vessel guidewire lumen;

14 advancing a branch vessel guidewire through the branch vessel guidewire
15 lumen and into the branch vessel;

16 aligning the side hole of the main vessel stent with the ostium of the
17 branch vessel by advancing the side member over the branch vessel guidewire and into
18 the branch vessel; and

19 inflating the balloon to deploy the main vessel stent after the side hole has
20 been aligned with the ostium.

1 22. A method as in claim 21, further comprising withdrawing the side
2 member from the branch vessel, advancing a branch stent deployment device over the
3 branch vessel guidewire, and deploying a branch vessel stent within the branch vessel
4 using the side member.

1 23. A method as in claim 22, further comprising retracting the side
2 member from the branch vessel while the catheter body remains within the main vessel.

1 24. A method as in claim 22, further comprising withdrawing the
2 catheter from the main vessel and the branch vessel prior to advancing the branch stent
3 deployment device.

1 25. A method as in claim 22, wherein the branch stent deployment
2 device comprises an elongate body having a balloon at a distal end, wherein the branch
3 stent is positioned over the balloon, and further comprising inflating the balloon to deploy
4 the branch stent.

1 26. A method as in claim 21, wherein the side member includes a
2 balloon at the distal end, and further comprising inflating the balloon to deploy a branch
3 stent that is disposed over the balloon on the side member.

1 27. A method as in claim 26, further comprising moving the side
2 member relative to the catheter body to position the branch stent prior to deployment.

1 28. A method as in claim 26, wherein the side member is fixedly
2 attached to the catheter body, and further comprising moving catheter to position the
3 branch stent prior to deployment.

1 29. A method as in claim 21, further comprising viewing relative
2 movement of a marker on the catheter body relative to a marker on the side member,
3 wherein relative movement indicates that the distal end of the side member that extends
4 out of the side hole of the main vessel stent is advancing into the ostium of the branch
5 vessel and that the side hole is aligning with the ostium of the branch vessel.

1 30. A method for positioning a main vessel stent at a vessel bifurcation
2 such that a side hole in the main vessel stent is in registry with an ostium of a branch
3 vessel, the method comprising:

4 providing a catheter comprising a catheter body having a distal end, a
5 proximal end, a main vessel guidewire lumen and a balloon disposed near the distal end
6 of the catheter body, with the main vessel stent being disposed over the balloon, and a
7 side member disposed adjacent the catheter body, the side member having a distal end, a
8 proximal end, and a branch vessel guidewire lumen, wherein a distal portion of the side
9 member is disposed beneath at least a portion of the main stent while being unattached to
10 the balloon, with the distal end of the side member extending out of the side hole;

11 introducing a main vessel guidewire into the main vessel lumen and a
12 branch vessel guidewire into the branch vessel lumen;

13 advancing the catheter through a main vessel to be near the vessel
14 bifurcation;

15 advancing the distal end of the side member over the branch guidewire and
16 into the branch vessel;

17 aligning the side hole of the main vessel stent with the ostium of the
18 branch vessel by further advancing the side member over the branch vessel guidewire and
19 into the branch vessel; and

20 inflating the balloon to deploy the main vessel stent after the side hole has
21 been aligned with the ostium.

1 31. A method as in claim 30, further comprising introducing the main
2 vessel guidewire into the main vessel and the branch vessel guidewire into the branch
3 vessel prior to the introduction of the main vessel guidewire and the branch vessel
4 guidewire into the catheter, and advancing the catheter over the main vessel guidewire
5 and the branch vessel guidewire.

1 32. A method as in claim 30, further comprising advancing the catheter
2 through the main vessel while also advancing the main vessel guidewire and the branch
3 vessel guidewire through the main vessel.

1 33. A method as in claim 32, further comprising advancing the catheter
2 through a guide catheter and stopping advancement of the catheter once in the vicinity of

3 a distal edge of the guide catheter, and advancing the main vessel guidewire further
4 through the main vessel and the branch vessel guidewire into the branch vessel.

1 34. A method as in claim 30, further comprising withdrawing the side
2 member from the branch vessel, advancing a branch stent deployment device over the
3 branch vessel guidewire, and deploying a branch vessel stent within the branch vessel
4 using the side member.

1 35. A method as in claim 34, further comprising retracting the side
2 member from the branch vessel while the catheter body remains within the main vessel.

1 36. A method as in claim 34, further comprising withdrawing the
2 catheter from the main vessel and the branch vessel prior to advancing the branch stent
3 deployment device.

1 37. A method as in claim 34, wherein the branch stent deployment
2 device comprises an elongate body having a balloon at a distal end, wherein the branch
3 stent is positioned over the balloon, and further comprising inflating the balloon to deploy
4 the branch stent.

1 38. A method as in claim 30, wherein the side member includes a
2 balloon at the distal end, and further comprising inflating the balloon to deploy a branch
3 stent that is disposed over the balloon on the side member.

1 39. A method as in claim 38, further comprising moving the side
2 member relative to the catheter body to position the branch stent prior to deployment.

1 40. A method as in claim 38, wherein the side member is fixedly
2 attached to the catheter body, and further comprising moving catheter to position the
3 branch stent prior to deployment.

1 41. A method as in claim 30, further comprising viewing relative
2 movement of a marker on the catheter body relative to a marker on the side member,
3 wherein relative movement indicates that the distal end of the side member that extends
4 out of the side hole of the main vessel stent is advancing into the ostium of the branch
5 vessel and that the side hole is aligning with the ostium of the branch vessel.

CATHETER WITH SIDE SHEATH

ABSTRACT OF THE DISCLOSURE

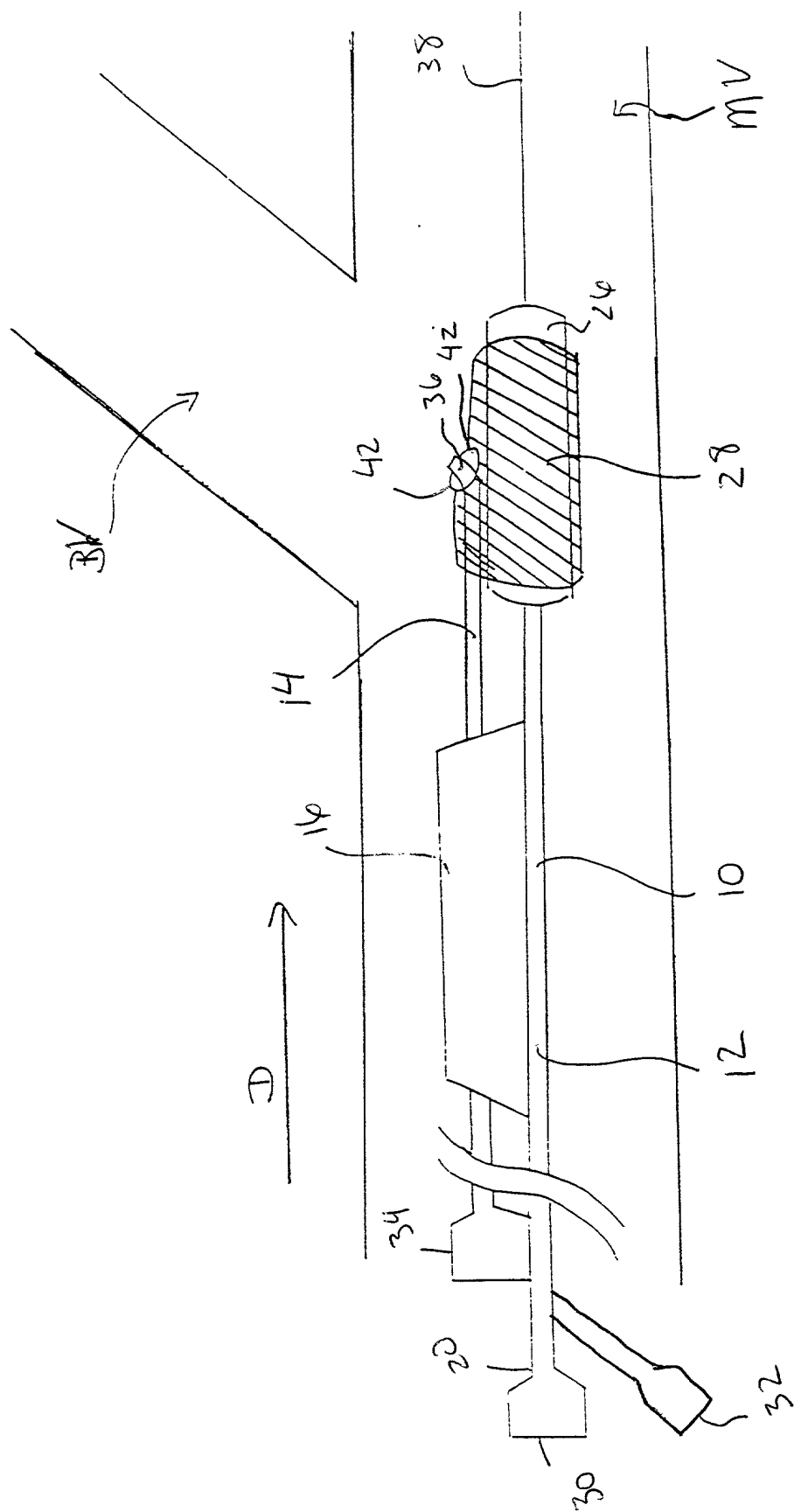
A catheter system comprises a catheter having a catheter body with a distal end, a proximal end, a main vessel guidewire lumen for receiving a main vessel guidewire and a balloon disposing at the distal end of the catheter body. The catheter further includes a side member that is disposed adjacent to the catheter body. The side member has a distal end, a proximal end, and a branch vessel guidewire lumen for receiving a branch vessel guidewire. A stent having a side hole is disposed over the balloon, and a distal portion of the side member is disposed beneath at least a portion of the stent while being adjacent to and movable with respect to the balloon.

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FIG. 2



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116.



Fig. 4

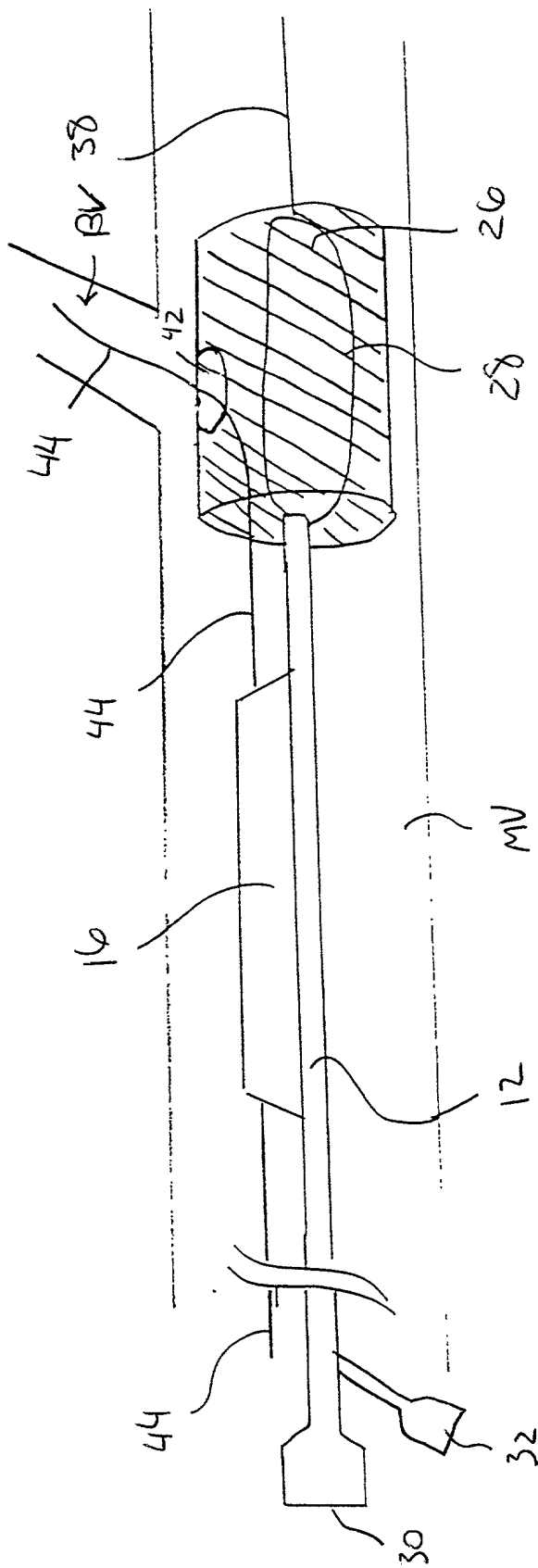
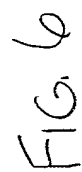
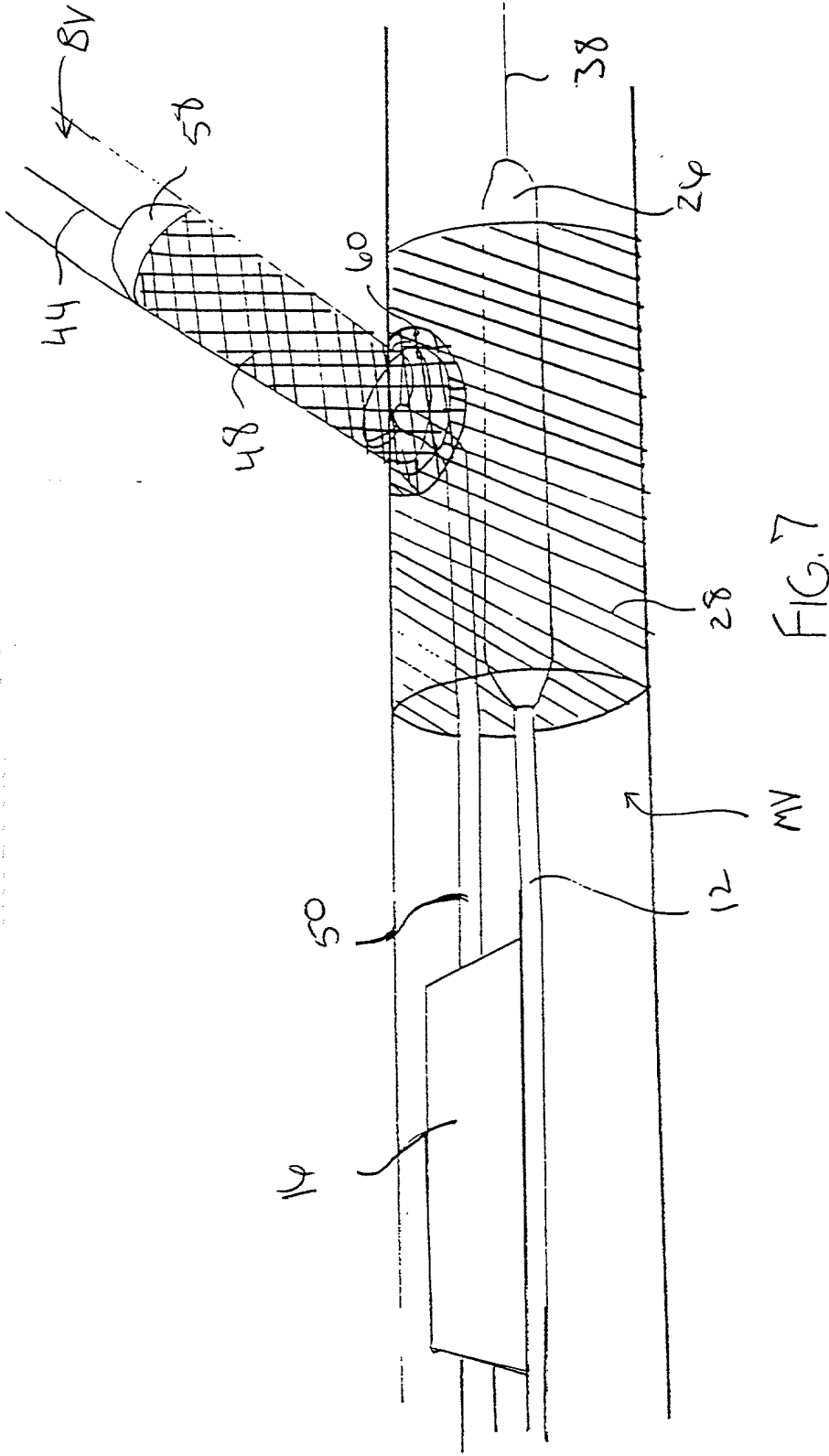


FIG. 5



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0	0	1	4	9	16	25	36	49	64	81	100	121	144	169	196	225	256	289	324	361	400	441	484	529	576	625	676	729	784	841	900	961	1024	1089	1156	1225	1296	1369	1444	1521	1600	1681	1764	1849	1936	2025	2116	2209	2304	2401	2500	2601	2704	2809	2916	3025	3136	3249	3364	3481	3600	3721	3844	3969	4096	4225	4356	4489	4624	4761	4900	5041	5184	5329	5476	5625	5776	5929	6084	6241	6400	6561	6724	6889	7056	7225	7396	7569	7744	7921	8100	8281	8464	8649	8836	9025	9216	9409	9604	9801	10000





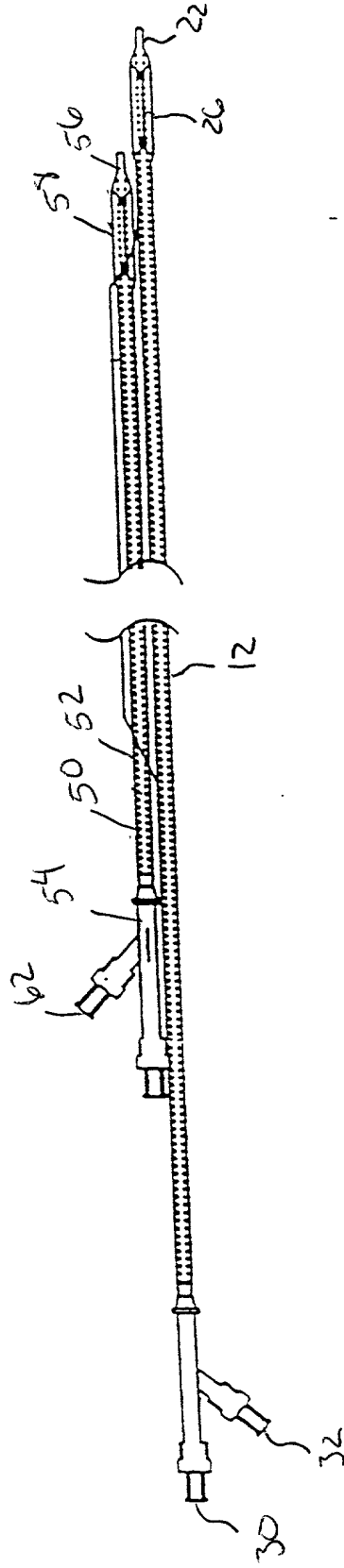


FIG. 9

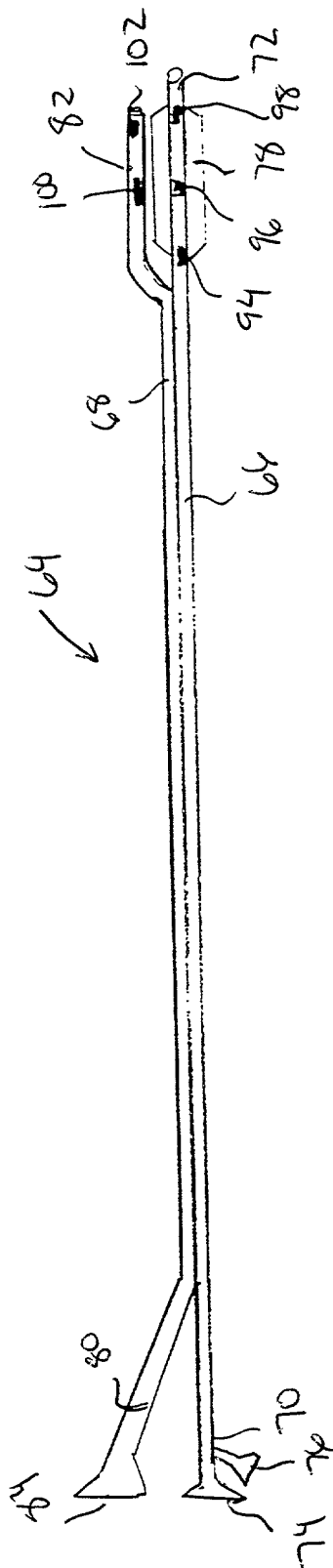


FIG. 10

FIG. 11

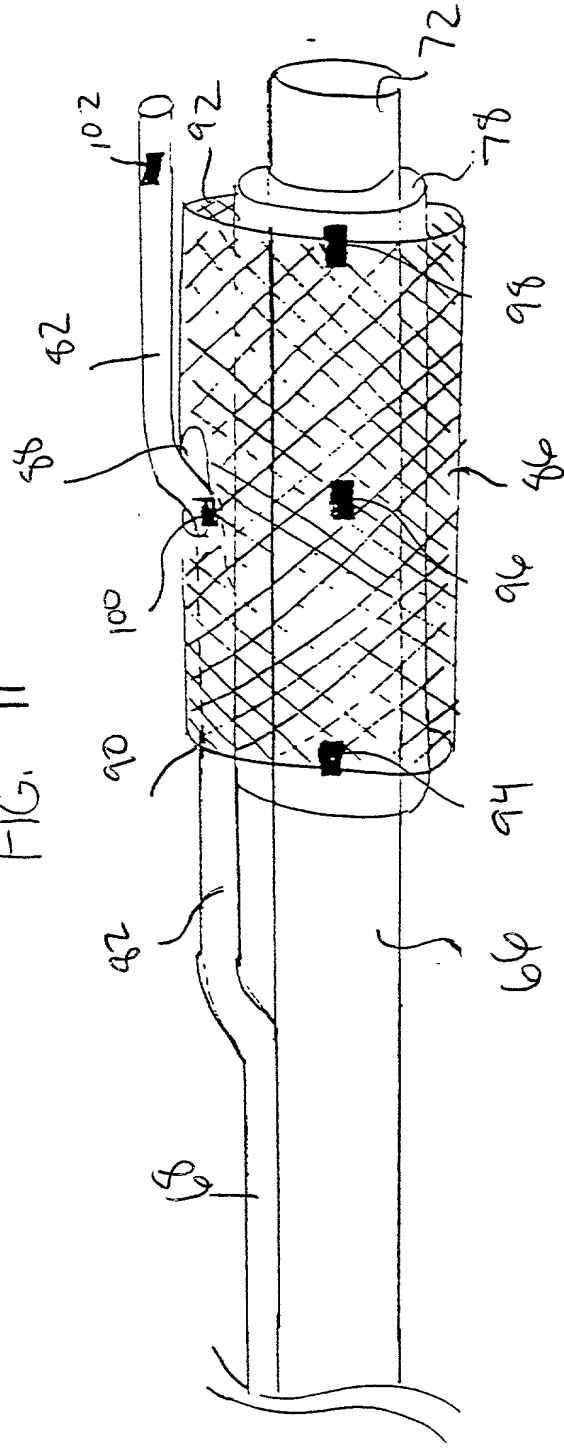
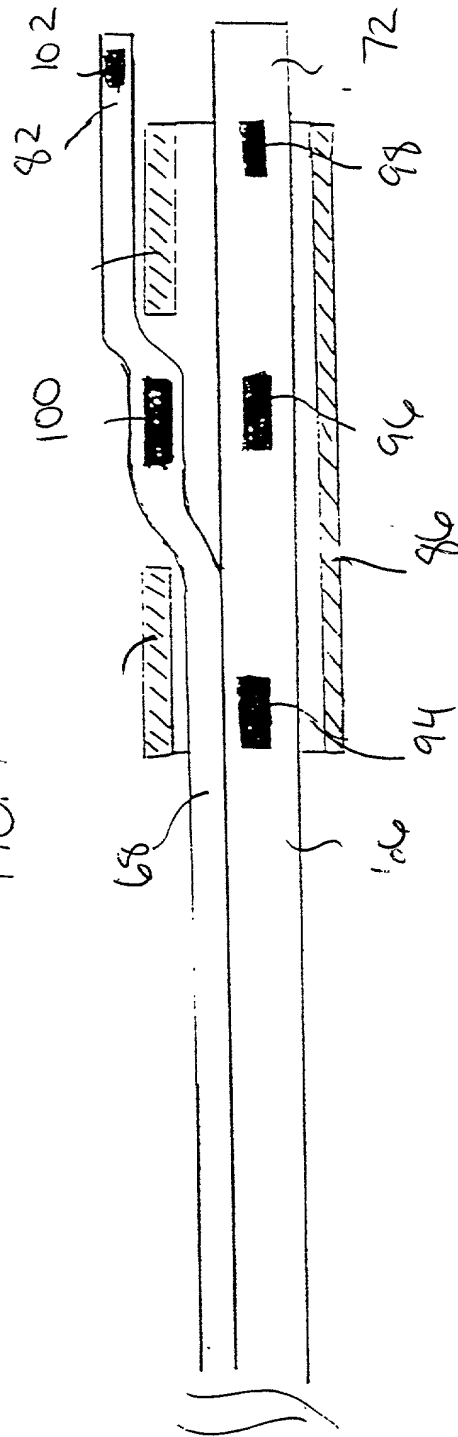


FIG. 12



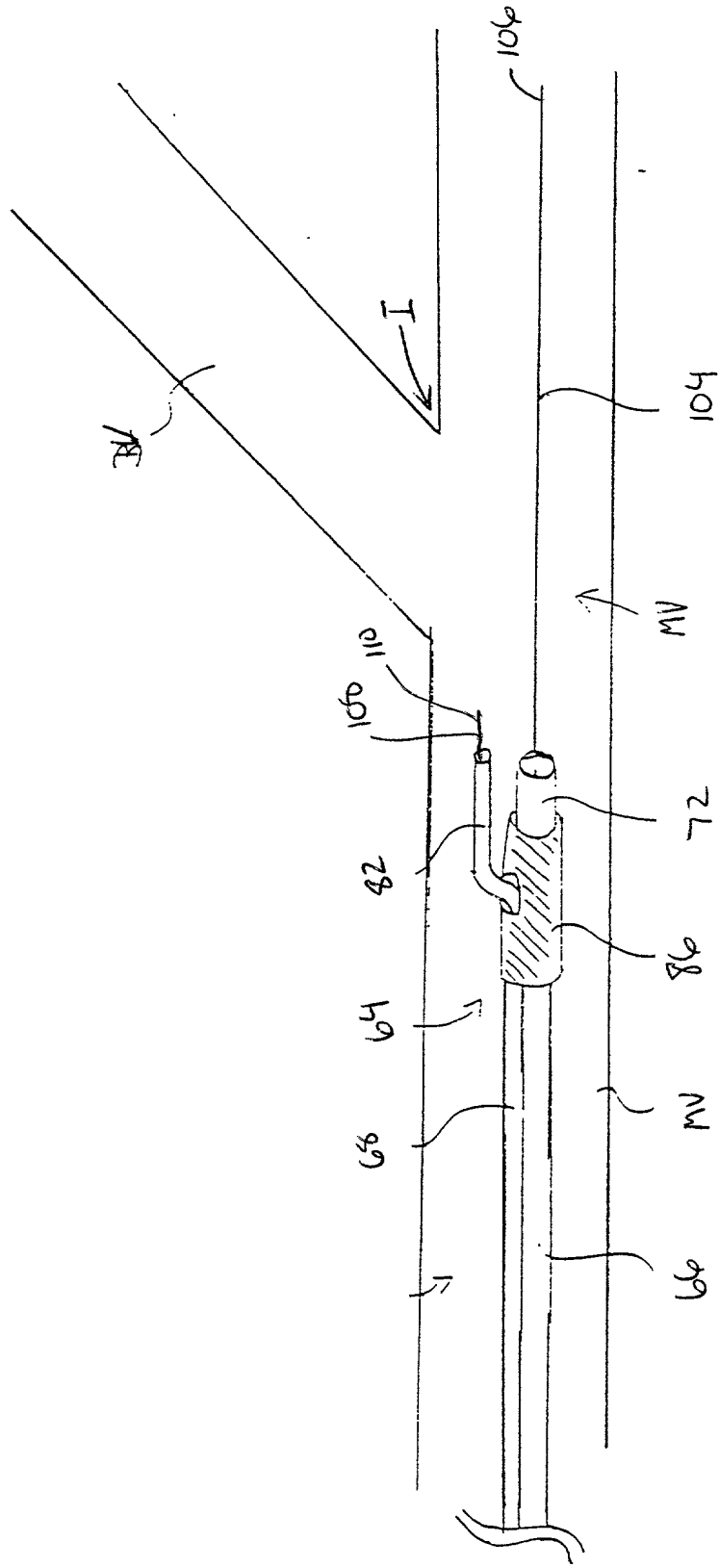


FIG. 13

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FIG. 14

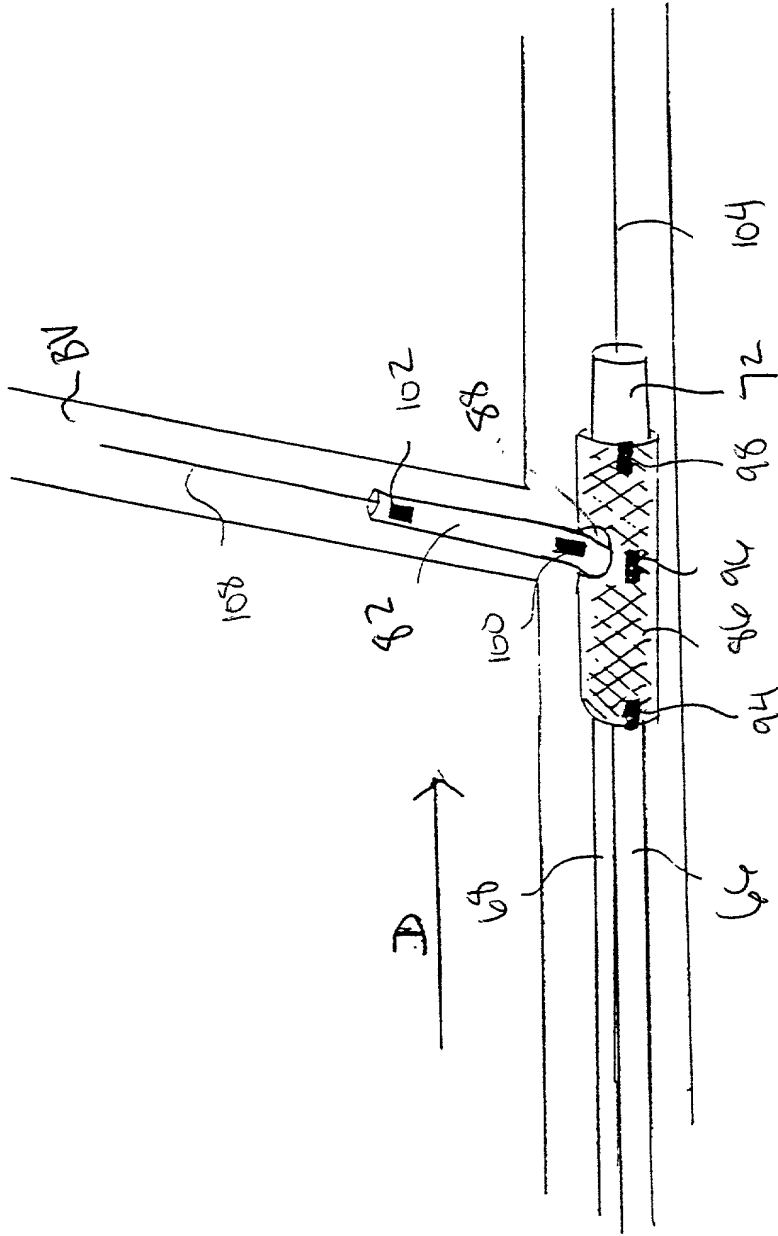


FIG. 15

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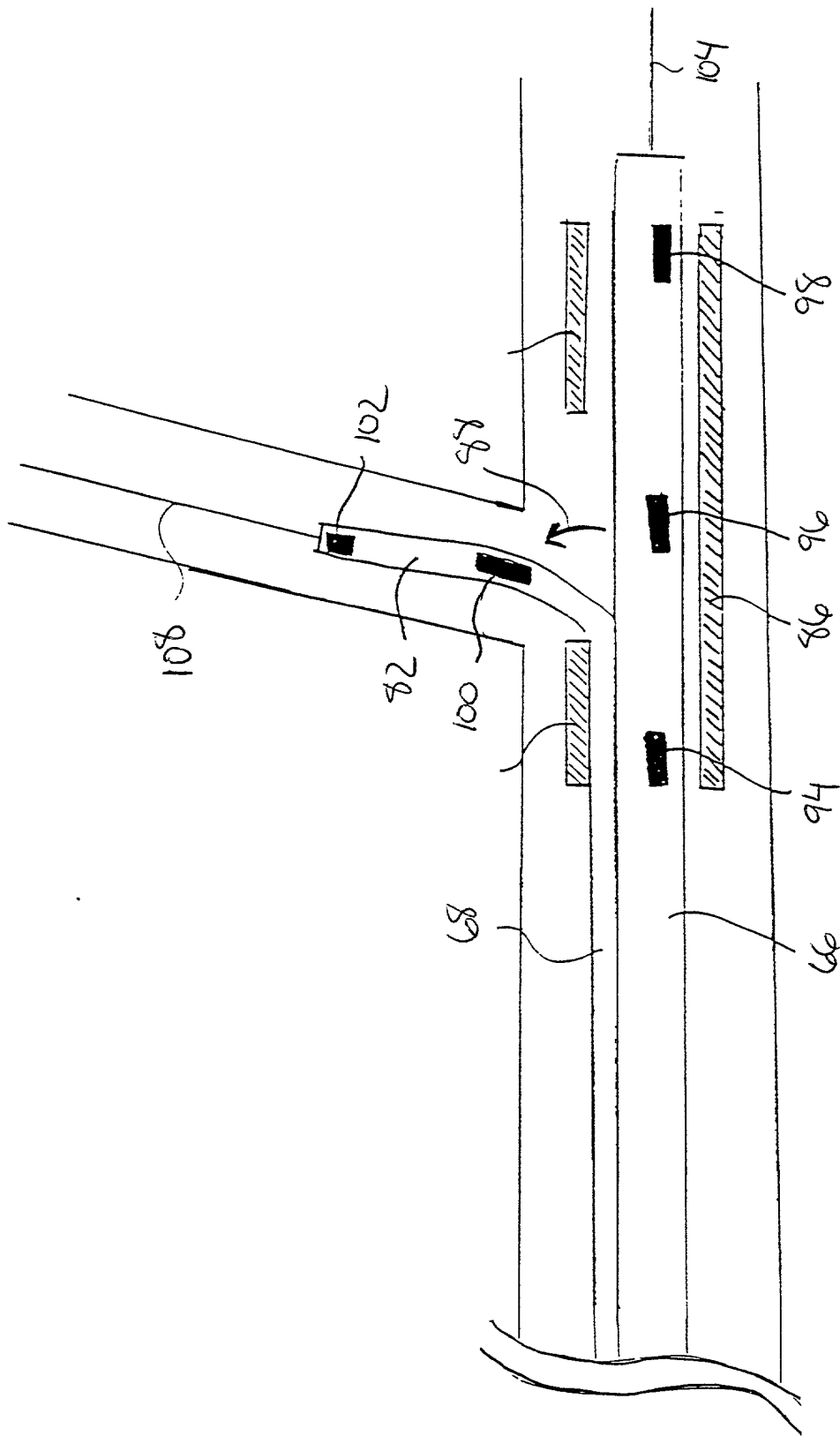


Fig. 14

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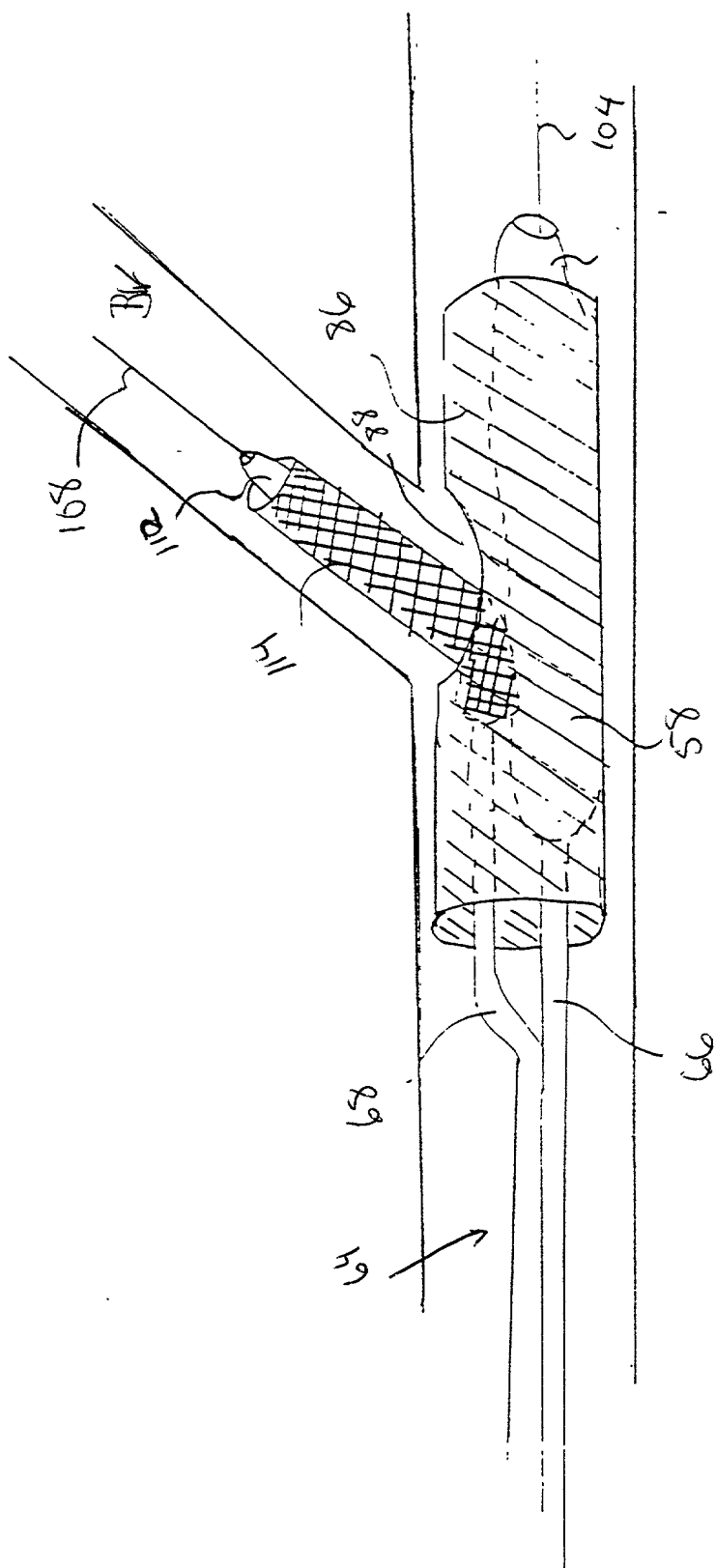
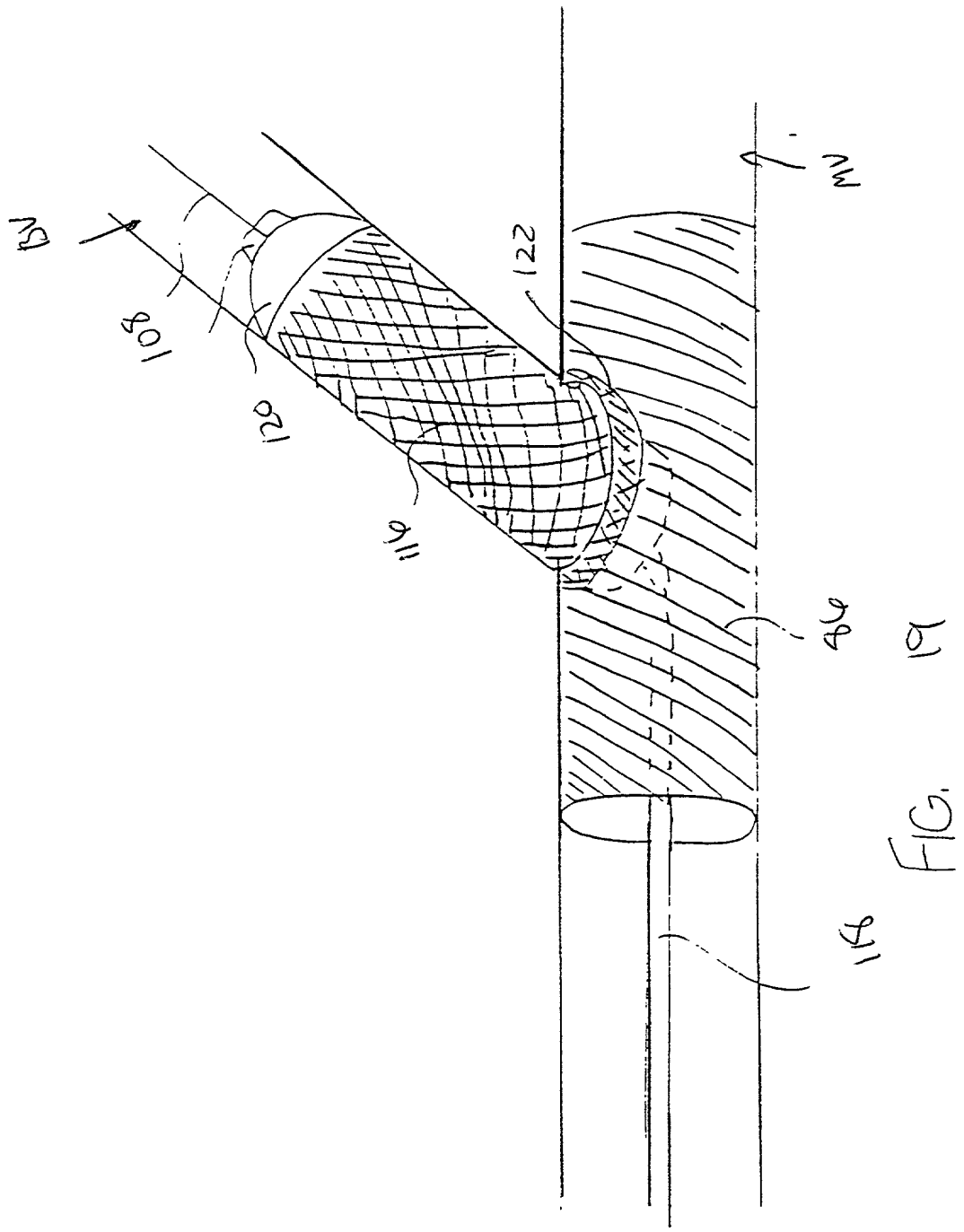


FIG. 17



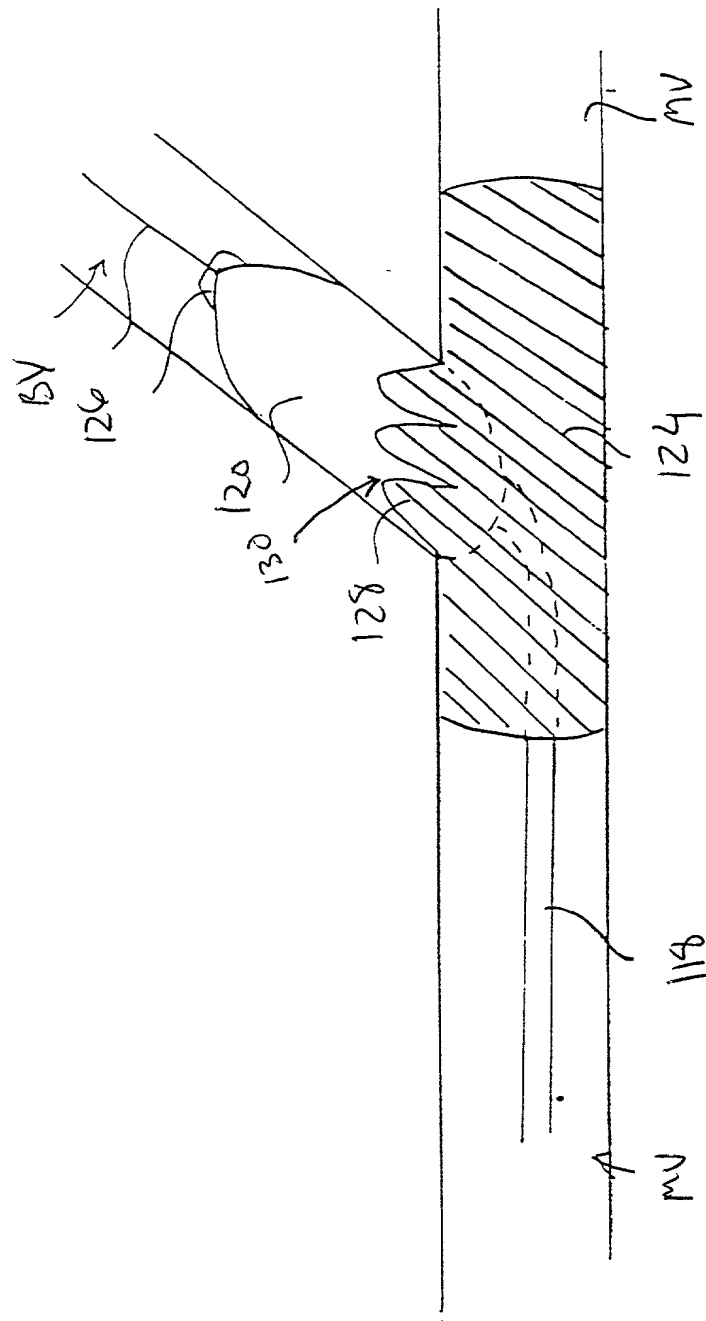


FIG. 20

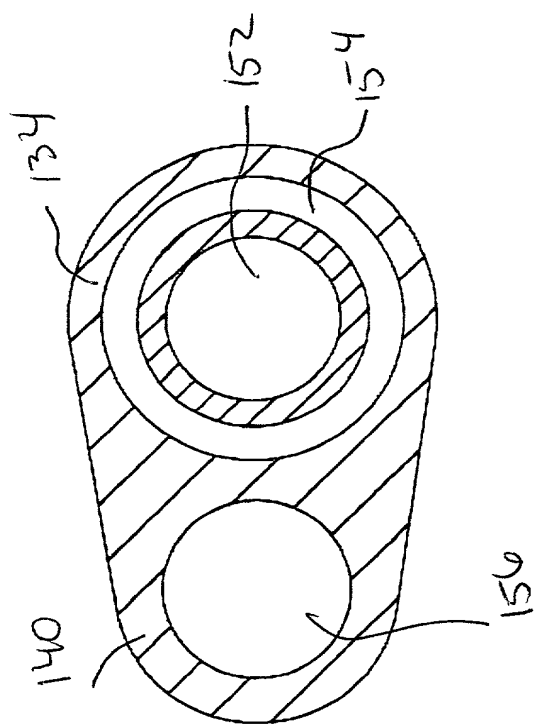


FIG. 22

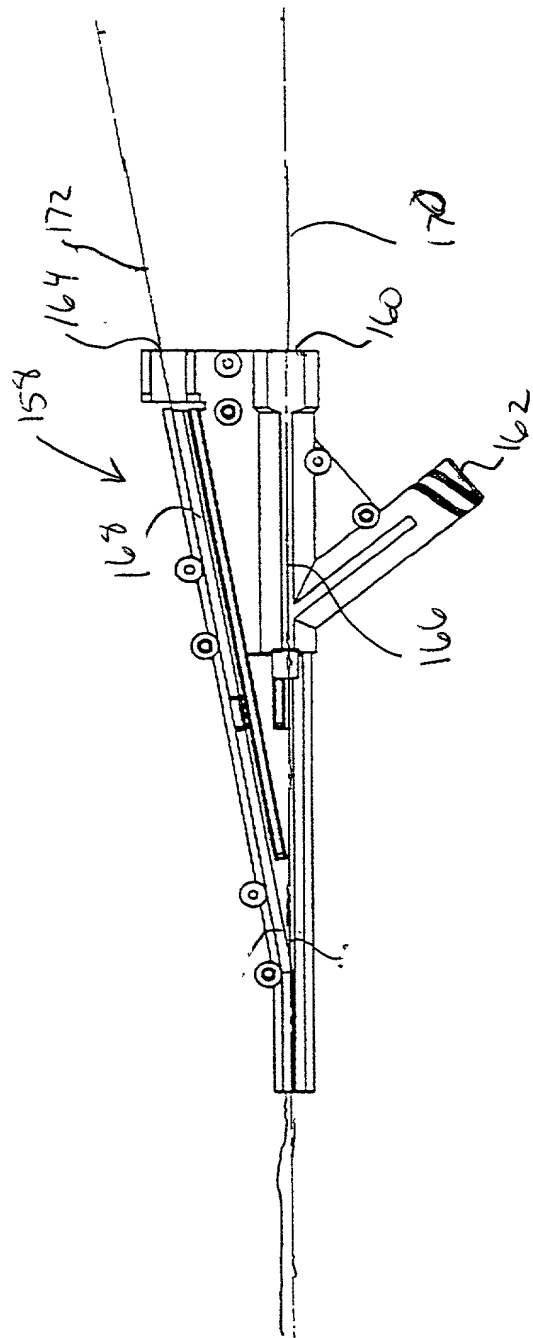


FIG. 23

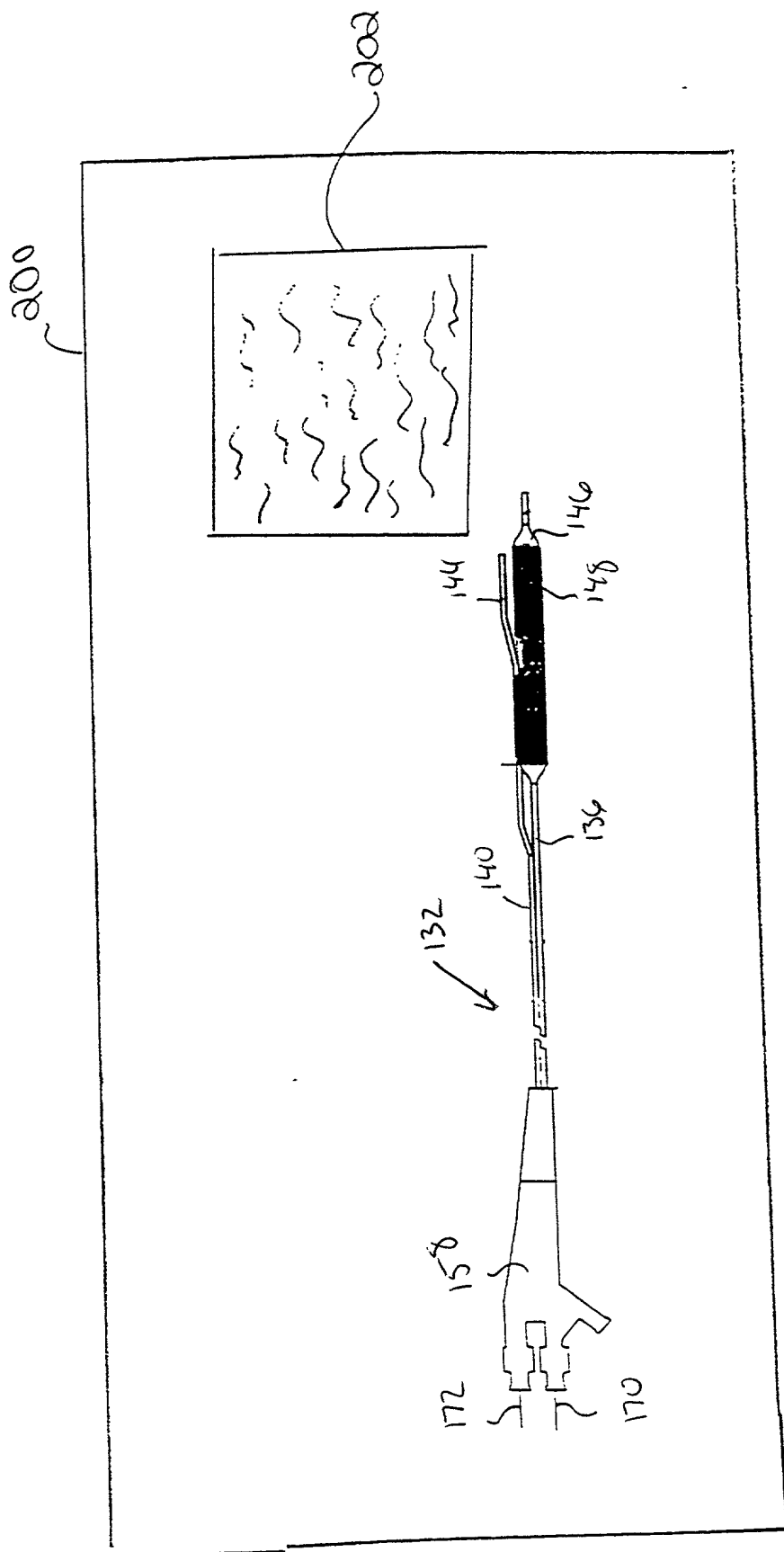


FIG. 24

DECLARATION

As a below named inventor, I declare that:

My residence, post office address and citizenship are as stated below next to my name; I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: **CATHETER WITH SIDE SHEATH AND METHODS** the specification of which X is attached hereto or was filed on as Application No. and was amended on (if applicable).

I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56. I claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

Country	Application No.	Date of Filing	Priority Claimed Under 35 USC 119

I hereby claim the benefit under Title 35, United States Code § 119(e) of any United States provisional application(s) listed below:

Application No.	Filing Date

I claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, Section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application No.	Date of Filing	Status
09/614,472	July 11, 2000	Pending
09/325,996	June 4, 1999	Pending
09/455,299	December 6, 1999	Pending

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Post Office Address:	Post Office Address: 14203 Stifel Lane Court	City: Town and Country	State/Country: Missouri	Postal Code: 63017
Full Name of Inventor 3:	Last Name: WILLIAMS	First Name: ERIC	Middle Name or Initial:	
Residence & Citizenship:	City: Fairfield	State/Foreign Country: California	Country of Citizenship: United States	
Post Office Address:	Post Office Address: 2068 Davis Drive	City: Fairfield	State/Country: California	Postal Code: 94533

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signature of Inventor 1 _____ Charles J. Davidson	Signature of Inventor 2 _____ Gil M. Vardi	Signature of Inventor 3 _____ Eric Williams
Date	Date	Date

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